

SEP 10 2008

TRANSMITTAL LETTER

In re Application of:  
DIEHL, Deborah L., et al

Serial No.: 10/783,078

Filed: February 20, 2004

For: DISSOLVABLE FILM COMPRISING AN  
ACTIVE INGREDIENT AND METHOD OF  
MANUFACTURE

Docket: SPG6612PDUS P1US

Group Art Unit: 1616

Examiner: Konata M. George

Confirmation No.: 6271

Mail Stop: Appeal Brief – Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

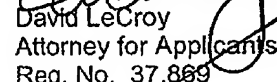
☒ Transmitted herewith find the document(s) related to this application.  
TRANSMITTAL LETTER and REPLY BRIEF

☐ Applicant hereby petitions for an extension of time under 37 CFR 1.136 of:

☐ One Month (\$120.00)☐ Two Months (\$450.00)☐ Three Months (\$1020.00)☐ Four Months (\$1590.00)

The total fee believed due is \$ 0.00. Please charge this amount and any other fees, which may be due (including filing fees under 37 CFR 1.16 and processing fees under 37 CFR 1.17) to Deposit Account No. 01-1350. If an extension of time is required but has not been requested above, Applicant hereby petitions for an extension of time sufficient for the attached document(s) to be timely. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

  
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CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office at (571) 273-8300 on September 10, 2008.

  
Diane L. Moxley

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**SEP 10 2008**

**PATENT APPLICATION**  
Attorney Docket No. 3049.SPD

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**APPLICANTS:** DIHEL, Deborah L. *et al.*  
**SERIAL NO.:** 10/783 078      **GROUP ART UNIT:** 1616  
**FILED:** 20 February 2004      **EXAMINER:** GEORGE, Konata M.  
**ENTITLED:** DISSOLVABLE FILM COMPRISING AN ACTIVE INGREDIENT AND  
METHOD OF MANUFACTURE

**CERTIFICATE OF TRANSMISSION UNDER 37 C.FR. §1.8**

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Diane Moxley

**Mail Stop Appeal Brief - Patents**  
**Commissioner for Patents**  
**Post Office Box 1450**  
**Alexandria, Virginia 22313-1450**

**REPLY BRIEF**

Dear Sir:

This is reply to the Examiner's Answer, which was mailed from the Office on 10 July 2008.

Examiner's Section (5) – Summary of Claimed Subject Matter

The Examiner states that the Brief is deficient in that Appellants state that claim 1 is the only independent claim, but claims 6 and 12 are also independent claims. Appellants acknowledge this oversight and provide the following remarks for the Board's consideration.

Claim 6 is as follows –

6. A dissolvable film having disposed on at least one surface thereof an encapsulated substance.

Dependent claims 7-11 depend therefrom. From claim 6 it is seen the invention of claim 6 is generally directed towards a dissolvable film having an encapsulated substance deposited on its surface (p. 3, lines 5-9). The film can be comprised of pullulan and/or starch, and the starch can be a modified starch such as hydroxyalkylated starch or succinated starch (p. 3, lines 9-14).

12. A method of preserving the flavor of an active to be delivered by a film, the method comprising encapsulating the active in a water soluble encapsulant and placing the encapsulated active on the surface of the film

Dependent claim 13 depends therefrom. From claim 12 it is seen that the present invention is also generally directed towards a method or process of preserving the flavor of an active that is delivered by a film (p. 4, lines 8-10). The process involves encapsulating the active in a water soluble encapsulant and placing the encapsulated active on the surface of the film (p. 4, lines 10-14). By preparing actives in this manner, flavors can be added to the film composition without losing their efficacy. Further, by encapsulating flavorings in water-soluble encapsulating material and then added to the film (p. 2, lines 15-25), dissolution of the capsule and release of the volatile is avoided.

Examiner's Section (9) – Grounds of Rejection

The Examiner urges, notwithstanding Appellant's Brief, is deficient in that Applicants claim that claim 1 is the

As previously noted, the Supreme Court continues to rely upon the *Graham* three pronged test in its consideration and determination of obviousness. In *KSR Int'l v. Teleflex Inc.*, 550 US \_\_\_, 82 USPQ 2d 1385, 1391 (Apr. 30, 2007) the Court stated –

While the sequence of these [Graham] questions might be reordered in any case, the factors continue to define the inquiry that controls. If a court, or patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under § 103.

*KSR*, 550 US \_\_\_, 82 USPQ 2d at 1391. The Court further stated –

To facilitate review, this analysis should be made explicit. *See In re Kahn*, 441 F.3d 977, 988 [78 USPQ2d 1329] (CA Fed. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”).

Leung teaches fast dissolving orally consumable films. Leung, however, fails to teach or suggest at least two unrelated elements of each independent claim of the present invention. Nowhere does Leung teach adding a substance after the film is made (1), or provide any motivation to do so. Further, with specific reference to dependent claims 2, 3 and 6-13 it has been admitted by the Examiner that Leung makes absolutely no reference to the use of encapsulated substances (2). In fact, Leung’s preferred method teaches away from the use of encapsulated substances in that Leung teaches preparing such volatile containing films without heating, as “heating results in undesirable losses of volatile ingredients to evaporation, which also affects the germ killing activity” of the film (col. 11, line 62 – col. 12, line 1).

From the above remarks of the Court, it is clear that an Examiner must provide support for a rejection under Section 103. Mere conclusory statements are not sufficient. In the present application, the Examiner has simply stated that, “[s]ince the claimed substance is volatile, it would have been obvious to one of ordinary skill in the art at the time the invention was made to encapsulate [the] volatile substance for the purpose of reducing the evaporation of the substance.” Applicants respectfully ask, if the solution recognized by Leung (*i.e.*, preparing films containing volatile substances without losing the substance to evaporation) was to prepare the films without heating, why didn’t Leung recognize Applicant’s solution of encapsulation? In the present case, the Examiner has merely stated a conclusory statement without providing evidentiary support that such products and methods of the present invention are indeed well known. Further, with respect to the step of adding a substance after a film is made, Leung again fails to recognize the benefit of such a process. Accordingly, the Examiner’s remarks constitute nothing more than impermissible use of hindsight based on Applicant’s own invention.

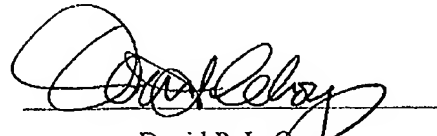
Conclusion

Appellants again submit that the claimed subject matter would not have been obvious to one skilled in the art from the disclosure of Leung. The Examiner has failed to establish a *prima facie* case of obvious under 35 U.S.C. § 103(a) and therefore the rejection under 35 U.S.C. § 103(a) should be reversed.

Respectfully submitted,

Dated: 10 Sept. 2008

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